FORM PTO-1390 (REV 5-93) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO (If known, see 37 CFR 1.5)
09/762923

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB99/02510	30 July 1999	13 August 1998

TITLE OF INVENTION
OPTICAL DEVICE

APPLICANT(S) FOR DO/EO/US
PARKER, Dawood

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1)
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☐ Other items or information:

"Express Mail" mailing label number EF 100061492 US
Date of Deposit February 12, 2001

I hereby certify that this paper is being deposited with the U.S. Postal Service "Express Mail-Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to: Hon. Commissioner of Patents and Trademarks, Washington, D. C. 20231.

Edwin D. Schindler

Edwin D. Schindler, Reg. No. 31,459

February 12, 2001
Date

Small Entity Decln. #3

Rec'd PCT/PTO 12 APR 2001

Applicant: Dawood Parker
Serial No.: 09/762,923
Filed:
For: OPTICAL DEVICE

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

[ ] the owner of the small business concern identified below:

[X] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Whitland Research Limited
ADDRESS OF CONCERN Whitland Abbey, Whitland
Carms SA34 0LG, United Kingdom

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled OPTICAL DEVICE by inventor Dawood Parker described in

[ ] the specification filed herewith
[X] P.C.T. Application No. PCT/GB99/02510, filed July 30, 1999
[ ] patent no. , issued

Small Entity Decln.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and now rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a non-profit organization under 37 CFR 1.9(e). NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME_____
ADDRESS _____
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN
[ ] NON-PROFIT ORGANIZATION

FULL NAME_____
ADDRESS _____
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN
[ ] NON-PROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in the loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))

I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Dawood Parker

TITLE OF PERSON OTHER THAN OWNER Managing Director

ADDRESS OF PERSON SIGNING Whitland Research Limited
Whitland Abbey, Whitland, Carms SA34 0LG, United Kingdom

SIGNATURE _____ DATE April 4, 2001

528 Rec'd PCT/PTO 12 FEB 2001

17. [X] The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5)): Search Report has been prepared by the EPO or JPO ..... $860.00 ~~$830.00~~	09/762923	
International preliminary examination fee paid to USPTO (37 CFR 1.482) **$640.00**		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).. **$710.00**		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37CFR 1.445(a)(2)) paid to USPTO..... **$950.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)..... **$90.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 860.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ -0-	

Claims	Number Filed	Number Extra	Rate		
Total Claims	-20 =		X $22.00	$ WILL REMIT	
Independent Claims	- 3 =		X $74.00	$ LATER	
Multiple dependent claims(s) (if applicable)			+ $230.00	$	
TOTAL OF ABOVE CALCULATIONS =				$ 860.00	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				$ -0-	
SUBTOTAL =				$ 860.00	
Processing fee of **$130.00** for furnishing the English translation later the ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$ -0-	
(BASIC FEE) **TOTAL NATIONAL FEE =**				$ 860.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ -0-	
TOTAL FEES ENCLOSED =				$ 860.00	
				Amount to be: refunded	$
				charged	$

a. [X] A check in the amount of $**860.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0450. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Edwin D. Schindler
Five Hirsch Avenue
P. O. Box 966
Coram, New York 11727-0966

Edwin D. Schindler
SIGNATURE

Edwin D. Schindler
NAME

31,459
REGISTRATION NUMBER

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: DAWOOD PARKER ART UNIT:

SERIAL NO.: 09/762,923 EXAMINER:

FILED: CONCURRENTLY HEREWITH

P.C.T. APPLICATION NO.: PCT/GB99/02510

EARLIEST PRIORITY CLAIMED: AUGUST 13, 1998

P.C.T. INTERNATIONAL FILING DATE: JULY 30, 1999

U.S. NATIONAL FEE PAID: FEBRUARY 12, 2001

TITLE: OPTICAL DEVICE

PRELIMINARY AMENDMENT

Hon. Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D. C. 20231

Dear Sir:

Prior to an examination on the merits of the above-identified patent application, please amend the above-identified application as follows:

"Express Mail" mailing label number EF 100061435 US
Date of Deposit April 16, 2001

I hereby certify that this paper is being deposited with the U.S. Postal Service "Express Mail - Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to: Hon. Commissioner for Patents, United States Patent and Trademark Office, Washington, D. C. 20231.

Edwin D. Schindler

Edwin D. Schindler, Reg. No. 31,459

April 16, 2001
Date

IN THE SPECIFICATION

Please amend the Specification as follows:

Page 1, immediately beneath the Title of the Invention, insert the following headings:

--BACKGROUND OF THE INVENTION--; and,

--Technical Field of the Invention--; and,

between lines 5-6 (as numbered along the left-hand margin of the page, which might not be the same as the actual number of lines on the page), insert the following heading:

--Description of the Prior Art--.

Page 2, between lines 20-22, insert the following heading:

--SUMMARY OF THE INVENTION--.

Page 9, line 25, insert the following heading:

--BRIEF DESCRIPTION OF THE DRAWING FIGURES--.

Page 10, between lines 6-8, insert the following heading:

--DETAILED DESCRIPTION OF THE DRAWING FIGURES AND EXPERIMENTAL DATA AND PREFERRED EMBODIMENTS --.

IN THE CLAIMS

Please cancel Claims 31 and 32, and amend the following claims to now read as follows:

1. (Amended) A sensor device for measuring blood oxygen saturation comprising light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged for providing signals corresponding to intensities of a respective wavelength of light received by the photodetector means.

2. (Amended) A sensor device according to Claim 1 characterised in that the sensor uses a plurality of wavelengths.

5. (Amended) A sensor device according to Claim 2 characterised in that the different wavelengths bear a predetermined relationship with each other.

10. (Amended) A sensor device according to Claim 7 characterised in that five wavelengths are isobestic and one wavelength provides the maximum absorption difference between oxygenated haemoglobin and deoxygenated haemoglobin.

19. (Amended) A method according to Claim 18 characterised in that the method comprises using a sensor device having light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged for providing signals corresponding to intensities of a respective wavelength of light received by the photodetector means.

27. (Amended) A method of monitoring of SIDS in infants comprising the steps of attaching a calibrated sensor to the skin of a patient and emitting white light, and detecting and measuring the scattered light, said calibrated sensor comprising light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged for providing signals corresponding to intensities of a respective wavelength of light received by the photo-detector means.

Please cancel Claims 29 and 30, and substitute the following claims therefor:

--33. A computer program for carrying out a method comprising the steps of collecting data, processing said data collected and displaying SO_2 and SaO_2 levels based on the data collected.

34. A computer program according to Claim 33, wherein said processing said data collected includes use of the algorithm:

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]},$$

wherein,

reflected absorptions (A) at wavelengths of 500 nm, 528 nm, 550 nm, 560 nm, 572 nm and 586 nm are used for calcula-

ting HbI and OXI according to the formulae of:

$HbI = (A_{528}-A_{520}) + (A_{550}-A_{528}) + (A_{572}-A_{550}) - (A_{586}-A_{572})$

$OXI = ((A_{550}-A_{50}-O) + (A_{572}-A_{560}))/HbI,$

and

SO_2 is calculated from the formula:

$SO_2 = 100 - (OXI - OXI_0)/(OXI_{100}-OXI_0),$

wherein,

OXI_0 and OXI_{100} are empirically determined for OXI and SO_2 values of 0% and 100% in skin.--

REMARKS

Prior to an examination on the merits of the above-identified patent application, please enter the foregoing preliminary amendments.

Claims 1-28, 33 and 34 are pending in the above-identified patent application. No amendments were entered during the P.C.T. international phase. Claims 1, 18, 27, 28 and 33 are presented in independent form.

By the present amendment, Claims 29-32 have been cancelled. Claims 33 and 34 recite the subject matter of prior Claims 31 and 32. The multiple dependency of Claim 10 has been deleted, and other formal amendments to the claims have been entered. Sectional headings have also been added to the Specification. The application is now in condition for a full examination on the merits. (A marked-up version of the

present claim amendments is attached to this Preliminary Amendment.)

Accordingly, an early examination on the merits and allowance are, therefore, respectfully requested and earnestly solicited.

Respectfully submitted,

DAWOOD PARKER

By Edwin D. Schindler

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April 16, 2001

VERSION OF AMENDMENTS WITH MARKINGS TO SHOW CHANGES MADE
(Dated April 16, 2001)

IN THE CLAIMS

Please cancel Claims 31 and 32, and amend the following claims to now read as follows:

1. (Amended) A sensor device for measuring blood oxygen saturation [which comprises] comprising light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged [to provide] for providing signals corresponding to [the] intensities of [the] a respective wavelength of light received by the photodetector means. [characterised in that the sensor device measured blood oxygen saturation.]

2. (Amended) A sensor device according to Claim 1 characterised in that the sensor uses a plurality of wavelengths.

5. (Amended) A sensor device according to Claim 2 characterised in that the different wavelengths bear a predetermined relationship with each other.

10. (Amended) A sensor device according to [Claims 7 or 9] Claim 7 characterised in that five wavelengths are isobestic and one wavelength provides the maximum absorption difference between oxygenated haemoglobin and deoxygenated

haemoglobin.

19. (Amended) A method according to Claim 18 characterised in that the method [includes the use of] comprises using a sensor device [of claim 1.] having light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged for providing signals corresponding to intensities of a respective wavelength of light received by the photodetector means.

27. (Amended) A method of monitoring of SIDS in infants [which comprises] comprising the steps of attaching a calibrated sensor [according to claim 1] to the skin of a patient and emitting white light, and detecting and [a] measuring the scattered light[.], said calibrated sensor comprising light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged for providing signals corresponding to intensities of a respective wavelength of light received by the photodetector means.

Please cancel Claims 29 and 30, and substitute the following claims therefor:

--33. A computer program for carrying out a method comprising the steps of collecting data, processing said data

collected and displaying SO_2 and SaO_2 levels based on the data collected.

34. A computer program according to Claim 33, wherein said processing said data collected includes use of the algorithm:

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]},$$

wherein,

reflected absorptions (A) at wavelengths of 500 nm, 528 nm, 550 nm, 560 nm, 572 nm and 586 nm are used for calculating HbI and OXI according to the formulae of:

$HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$

$OXI = ((A_{550} - A_{0-O}) + (A_{572} - A_{560}))/HbI,$

and

SO_2 is calculated from the formula:

$SO_2 = 100 - (OXI - OXI_0)/(OXI_{100} - OXI_0),$

wherein,

OXI_0 and OXI_{100} are empir8ically determined for OXI and SO_2 values of 0% and 100% in skin.--

MARKED-UP AMENDMENT-3

OPTICAL DEVICE

This invention relates to an optical device for monitoring or measuring/displaying the arterial oxygen saturation with motion artefact suppression and to a novel medical technique for providing arterial oxygen saturation data.

Monitors are available which use non-invasive optical techniques to measure the arterial oxygen saturation in patients. For example, it is known, that in order to measure blood oxygen saturation, it is necessary to provide a device which passes light through biological tissue, such as the human finger, and to monitor the transmitted or reflected output signal from a photodetector of this device continuously. Such devices are described, inter alia, in International Patent Application No WO94/03102.

As is well known in the art, these instruments suffer interference due to patient movement, i.e. motion artefact.

Movement of the subject leads to a change in the length of the path of the light through the biological tissue and hence to a variation in the intensity of light received by the photodetector. This renders the device incapable of distinguishing between changes in received light intensity caused by variations in light absorption by the component being monitored (eg oxygen in the blood), and changes in received light intensity caused by variations in the light pathlength due to movement of the subject. The problem is common to all optical monitoring devices and can render these devices inoperative for long periods of time. The problem is particularly severe in critical health care applications, were continuous monitoring is essential.

The device described in WO 94/03102 attempts to address the problem of the motion artefact in measuring SaO_2 by using an additional wavelength to enable the motion artefact to be cancelled. Although WO 94/03102 broadly describes the use of a plurality of wavelengths (including the n+1 motion artefact wavelength) the device

exemplified uses three wavelengths, namely, a pulse rate wavelength, an SaO_2 wavelength and a motion artefact wavelength. However, in practice, the three wavelengths proposed in WO 94/03102 are not sufficient to overcome motion sensitivity.

Generally, medical practitioners desire to measure arterial oxygen saturation (SaO_2). For example, conventionally used pulse oximeters measure SaO_2. We have now devised an optical measuring or monitoring device which is able to monitor or measure blood oxygen saturation (SO_2) and display the arterial blood oxygen saturation non-invasively and to suppress the effects of motion artefact.

Furthermore, existing optical devices do not take into account the variations in transmitted light with varying skin colours. Melanin is present in increasing concentrations from fair through brown to black skin. The peak of its absorption spectrum is at 500nm decreasing almost linearly with increasing wavelength. Melanin is present in the epidermis, thus, in very high concentrations as is the case in black skin, it can mask the absorption of haemoglobin in the dermis. Even in brown skin, the absorption by melanin is superimposed on that of haemoglobin so that any algorithm which uses the shape of the absorption spectrum in order to produce SO_2 value needs to compensate for this fact.

Thus, we have also devised an optical measuring or monitoring device which is capable of compensating for variations in melanin levels in the skin.

In accordance with this invention, there is provided a sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measures blood oxygen saturation.

The sensor of the invention may use a spectral wavelength of from 526 to 586 nm.

In a preferred embodiment of the invention the light beam will emit a plurality of wavelengths, the arrangement being such that the signal levels corresponding to the different wavelengths bear a predetermined relationship with each other. A particular advantage of the sensor of the invention is that it only enables a user to compare "slopes" on a graph and the use of a range of different wavelengths allows for a more accurate determination without an increase in costs. In a preferred embodiment of the invention 3 or more different wavelengths are used, the optimum number of wavelengths is 5 or 6 and preferably 6.

It is also an important feature of the present invention that at least one or more of the wavelengths used are isobestic wavelengths. For the sake of clarity, by the term isobestic wavelength we mean a wavelength at which oxygenated haemoglobin and deoxygenated haemoglobin absorb the same amount of light. In a preferred embodiment substantially most of the wavelengths used are isobestic wavelengths. When six wavelengths are used it is preferred that five of them are isobestic wavelengths. In this preferred embodiment the sixth wavelength is one at which there is maximum difference between the absorption of light of oxygenated haemoglobin and deoxygenated haemoglobin.

Generally the device and technique of the present invention measures oxygen saturation (SO_2) ie the value of oxygen saturation in venous and arterial tissue combined. Because oxygen saturation in venous tissue is usually low it is well known that the value of SO_2 is less than that of SaO_2. In the technique of the invention we call the difference the scaling factor Δ, such that

$$SaO_2 - SO_2 = \Delta$$

Thus the technique of the invention initially measures SaO_2 using a conventional arterial blood oxygen meter eg a pulse oximeter. SO_2 is then measured to determine

and thus subsequently SO_2 measurements made using the device of the invention are corrected by the value of Δ. Furthermore, the device and technique of the invention continually, although intermittently, allows SaO_2 and thereby Δ to be checked.

The sensor device of the invention is generally an optical measuring or monitoring device.

The sensor may be attached to the chest or abdomen of an infant. The tip of the sensor may incorporate a mirror and is provided with an optical fibre light transmitting cable such that the fibre cable lies flat on the surface of the skin. White light (20 to 50W quartz halogen light bulb) is preferred and is transmitted along an optical fibre to the skin where multiple scattering occurs as photons interact with cellular and subcellular particles. Light can be absorbed by the haemoglobin present in the blood flowing in the tissue below the sensor before being scattered back along receiving optical fibres. The scattered light can be transmitted along a plurality eg in the preferred embodiment 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm (green/yellow visible light) and especially between 526 and 586. Generally, the number of detectors should be the same as the number of transmitting fibres. The sensor may optionally be heated above normal body temperature, to eg 40°C and up to 42°C for short periods the temperature may even reach 44°C. Alternatively, a single fibre of from 50 to 150nm in diameter may be used with one to three white LEDs.

Although the sensor of the invention may be adapted to operate with either transmitted light or reflected light, it is preferred that it operates on reflectance (remittance). Thus in contrast to, eg a pulse oximeter the transmitters and the sensors are situated on the same side of the tissue when in use.

According to a further feature of the invention we provide a "hand held" sensor device as hereinbefore described.

In particular, in the "hand held" sensor of the invention the optical fibre transmitting cable(s) may be replaced by a light emitting diode (LED) which significantly reduces the complexity of the sensor.

Before use, the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures. Signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

In the preferred embodiments, the use of 6 wavelengths gives the technique a considerable advantage over the pulse oximetry method which uses the minimum number of wavelengths necessary to obtain the information required. The use of more wavelengths in our method gives the technique stability against spurious disturbances at a particular wavelength, enables flexibility in the algorithm to cope with factors such as skin colour. Nevertheless, the sensor of the invention can utilise either oximetry or pulsed oximetry.

Averaging of the signal over a second or more also removes motion artefacts. It is also the case that the technique operates in the visible wavelength range. Thus, although the penetration of light into tissue is much less, the influence of poor contact with the tissue may also be considerably less thus reducing movement artefact. It is important to emphasis that our technique does not measure pulsatility as in the case in pulse oximetry.

SO_2 is the ratio of the oxyhaemoglobin concentration $[HbO_2]$ to the total concentration of haemoglobin ($[HbO_2]$ + [Hb], where [Hb] is haemoglobin concentration) expressed as a percentage.

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation

The reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:

$$HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$$
$$OXI = ((A_{550} - A_{50}O) + (A_{572} - A_{560})) / HbI$$

SO_2 is calculated from the formula:

$$SO_2 = 100 = (OXI - OXI_o) / (OXI_{100} - OXI_o)$$

Where OXI_o and OXI_{100} are empirically determined values for OXI at SO_2 values of 0% and 100% in skin. HbI is the haemoglobin index such that

$$HbI \times k = [Hb]$$

where k is a constant.

The spectral range used for the algorithm is from 526 to 586nm and 22 absorption values are recorded within that range. The first process is to carry out a Kubelka and Monk transformation which reduces the intrinsic effect of the scattering of light within the skin.

The following operation is carried out:

$$\text{K-B Transformed spectrum} = 0.5 \times (R^2)/(1-R)$$

where R is the remitted spectrum (Reference: Kubelka, P and Munk F, Ein eitrag zur Optik der Farbanstriche, Zeitschrift fur technische Physik, 11a:593-601 (1931)).

In a paper presented by Wolfgang Dümmler in 1988, he describes that, according to the Kubelka-Munk theory (see Section II.2), the remission of an infinitely thick sample is dependent only on the quotients of absorption and scattering coefficients and is given by:

$$R_\infty = A/S + 1 - \sqrt{\{A/S\ (A/S + 2)\}}$$

The equation can be solved explicitly according to A/S

$$A/S = 0.5\ (R_\infty + 1/R_\infty) - 1$$

where R is the remitted spectrum that is the spectrum of light scattered back from the skin.

The transformed spectra are then "straightened" by subtracting the interpolated straight line joining the absorption values at the isosbestic wavelengths of 526 and 586nm. This, in part compensates for the melanin concentration.

The straightened spectra are normalised by division by the integral of the absorption values from 526 to 586nm.

The algorithm can make use of two reference spectra. These spectra may be from whole blood (measured in a cuvette) or spectra recorded in skin or the mean spectra recorded from several individuals. One reference spectrum is of fully oxygenated haemoglobin the other is of fully deoxygenated haemoglobin. The fully oxygenated spectrum is obtained by equilibration of whole blood in the cuvette with 95% oxygen and 5% CO_2 at 37°C or, in skin of the forefinger heated to 44°C at maximal reactive hyperaemia following release of the inflatable cuff after 6 minutes of brachial artery

occlusion. The fully deoxygenated spectrum is obtained by equilibration of whole blood in the cuvette with 95%N_2 and 5% CO_2 at 37°C or, in skin of the forefinger heated to 44°C at the end of a 6 minute period of brachial artery occlusion prior to release of the inflatable cuff. The reference spectra are K-M transformed, "straightened" and normalised as described above.

An iterative process sequentially "mixes" the two references spectra in increments of 1% until the best least squares fit is achieved with the measured spectrum using all the absorption values at the 22 wavelengths. The iteration typically starts by adding 100 parts of the fully oxygenated spectrum to 0 parts of the fully deoxygenated spectrum, then 99 parts of the fully oxygenated spectrum to 1 part of the fully deoxygenated spectrum and so forth until the sum of the squares of the differences between the measured absorption values and those obtained by combining the reference spectra reaches its minimum value. The resultant SO_2 value is the proportion of the oxygenated reference spectrum in the best fitted spectrum (eg 80 parts of the fully oxygenated spectrum with 20 parts of the fully deoxygenated spectrum would give an SO_2 value of 80%).

A maximum limit on the least squares value is stipulated such that noise or artefacts in the recorded spectra lead to the rejection of the SO_2 value.

A further important aspect of this invention is the fact that our technique measures arterial blood oxygen saturation. This is achieved in the following way: at normal skin temperature an optical measurement made on the skin of a patient would measure the oxygen saturation of a mixture of venous and arterial blood in the capillaries. In our technique we heat the skin below the sensor to below 40°C. The effect of this application of heat is to cause an increase in skin blood flow, sufficient to cause the oxygen saturation of the blood in the capillaries in the skin to equilibrate with the arterial blood supply. In this way the optical device will measure the equivalent of arterial blood oxygen saturation.

According to a further feature of the invention we provide a method of monitoring of SIDS in infants which comprises attaching a calibrated sensor as hereinbefore described to the skin of a patient and emitting white light, detecting and a measuring the scattered light.

According to a further feature of the invention we provide a sensor device which measures SO_2 as hereinbefore described coupled to an oximeter eg a pulse oximeter, which is conventionally known per. The sensor device of this embodiment will measure SO_2, while the pulse oximeter will measure SaO_2, at least intermittently, and allowing the scaling factor Δ to be calculated and intermittently monitored. Thus the sensor device of this embodiment measures SO_2 but displays SaO_2.

Thus according to a yet further feature of the invention we provide a method of SaO_2 monitoring which comprises measuring SO_2 and adding a scaling factor Δ as hereinbefore defined.

The method of the invention preferentially comprises the use of a sensor device of the invention. In the most preferred method, the sensor is used to continually measure SO_2 and to intermittently measure SaO_2 allowing the motion artefact to be annulled.

In a further embodiment, the method of the invention as hereinbefore described includes the use of the Kubelka and Monk transformation to account for melanin levels in skin.

The invention will now be described by way of example only and with reference to the accompanying drawings in which Figure 1 is a schematic representation of the optical measurement method of the invention;

Figures 2(a) and 2(b) are both graphs which illustrate how the SO_2 values are calculated;

Figure 3 is a "hand held" sensor according to the invention;

Figure 4 is a representation of the schematic layout of the optical system of the sensor of the invention;

Figure 5 is a representation of the hand held sensor of the invention in use; and

Figure 6a to d are graphs representing measured SO_2 values for different skin colours.

With reference to Figure 1, an optical blood saturation sensor (1) comprises transmitting fibres (2) from a lamp (not shown) which transmit light to be reflected from a mirror (3) onto the skin (4) of a patient where the light in proportions is absorbed and scattered or reflected depending upon the oxygen content of the haemoglobin and the wavelengths of light used. Reflected light (5) is detected by receiving fibres (6) and transmitted to a photometer (not shown).

The measurement technique can best be understood by reference to Figures 2(a) and 2(b). Analysis of the data to obtain an index of haemoglobin concentration and arterial oxygen saturation (SaO_2) is carried out as follows: the gradients between 5 isobestic wavelengths (500, 520, 548, 575 and 586nm) are added to given an index which is related to the haemoglobin concentration. This index is used to normalise the measured tissue spectra. The oxygen saturation (SO_2) is calculated from the gradients between the absorption peaks for de-oxygenated haemoglobin (560nm) and the two adjacent isobestic wavelengths (548 and 575nm) of the normalised spectra.

The most important factor influencing the stability of the SaO_2 lies in our 6 wavelength analysis technique which incorporates the 5 isobestic wavelengths and the single oxygenated/deoxygenated peak. The two accompanying Figures illustrate how the HbI and SO_2 values are obtained from the spectra. HbI is the sum of the moduli of the slopes of the lines connecting the isobestic points as shown in the first Figure 2(a): it can be seen that any change in the general level of the signal, such as may occur due to small changes in the distance of the probe from the skin would not

have any significant influence on this value. The absorption spectrum may shift up or down, but the sum of the moduli of the slopes remains constant.

SO_2 values (Figure 2(b)) are calculated from the sum of the moduli of the slopes of the extinction values between the neighbouring isobestic points and the deoxygenated peak, normalised to the HbI value. We thus obtain not only an SO_2 value but, on the way, we can also obtain a measure of relative haemoglobin concentration (HbI) from our measurements.

With reference to Figure 3 a hand held sensor (7) may comprise a fibre optic cable (8), a prism (9), an LED (10) and a heater and temperature sensor (11). The sensor (7) is provided with insulation (12).

With reference to Figure 4, a sensor (13) is provided with 6 fibre bundles (14), a light source (15) and a thermistor (16).

CLAIMS

1. A sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measured blood oxygen saturation.

2. A sensor device according to Claim 1 characterised in that the sensor a plurality of wavelengths.

3. A sensor device according to Claim 2 characterised in that the sensor uses a spectral wavelength of from 500 to 600 nm.

4. A sensor device according to Claim 3 characterised in that the sensor uses a spectral wavelength of from 526 to 586 nm.

5. A sensor device according to Claim 2 characterised in that the different wavelengths bear a predetermined relationship with each other

6. A sensor device according to Claim 2 characterised in that the sensor uses 3 or more different wavelengths.

7. A sensor device according to Claim 6 characterised in that the number of wavelengths used is 5 or 6.

8. A sensor device according to Claim 2 characterised in that at least one of the wavelengths is an isobestic wavelength.

9. A sensor device according to Claim 8 characterised in that most of the wavelengths are isobestic wavelengths.

10. A sensor device according to Claims 7 or 9 characterised in that five wavelengths are isobestic and one wavelength provides the maximum absorption difference between oxygenated haemoglobin and deoxygenated haemoglobin.

11. A sensor device according to Claim 7 characterised in that the number of wavelengths used are selected from 500, 528, 550, 560, 572 and 586 nm.

12. A sensor device according to Claim 7 characterised in that the scattered light is transmitted along 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm.

13. A sensor device according to Claim 12 characterised in that the optical filters are all in the range 526 and 586 nm.

14. A sensor device according to Claim 7 characterised in that the scattered light is transmitted along a single fibre of from 50 to 150nm in diameter used with one to three white LEDs.

15. A sensor device according to Claim 1 characterised in that it operates on reflectance (remittance).

16. A sensor device according to Claim 1 characterised in that is a "hand held" sensor device.

17. A sensor device according to Claim 1 characterised in that it is coupled to an oximeter.

18. A method of SaO_2 monitoring which comprises measuring SO_2 and adding a scaling factor Δ.

19. A method according to Claim 18 characterised in that the method includes the use of a sensor device of claim 1.

20. A method according to Claim 18 characterised in that the sensor is used to continually measure SO_2 and to intermittently measure SaO_2.

21. A method according to Claim 18 characterised in that the Kubelka and Munk transformation is used to account for melanin levels in skin.

22. A method according to claim 21 characterised in that the method involves the use of an algorithm;

$$\text{K-B Transformed spectrum} = 0.5 \times (R^2)/(1-R)$$

where R is the remitted spectrum,

and which involves the steps of measuring the remitted spectrum from a light source measuring arterial blood flow.

23. A method according to claim 18 characterised in that the method the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures.

24. A method according to claim 18 characterised in that signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

25. A method according to claim 18 characterised in that more than 22 absorption values are recorded within that range 526 to 586nm.

26. A method according to claim 18 characterised in that one reference spectrum is of fully oxygenated haemoglobin the other is of fully deoxygenated haemoglobin.

27. A method of monitoring of SIDS in infants which comprises attaching a calibrated sensor according to claim 1 to the skin of a patient and emitting white light, detecting and a measuring the scattered light.

28. A data collection, processing and display system comprising the parameters of code number protection, sampling parameters, supply air flow rates, chamber pressure, exhaust air flow rates, top timer bar, bottom set-up bar and file identification bar.

29. A computer programme product adapted for absorption data collection, processing and display of SO_2 and SaO_2 levels.

30. A computer programme product according to claim 26 characterised in that the processing includes the use of the algorithm:

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation

wherein the reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:

$$HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$$

$$OXI = ((A_{550} - A_{50}O) + (A_{572} - A_{560})) / HbI$$

and

SO_2 is calculated from the formula:

$$SO_2 = 100 = (OXI - OXI_o) / (OXI_{100} - OXI_o)$$

wherein OXI_o and OXI_{100} are empirically determined values for OXI at SO_2 values of 0% and 100% in skin.

31. A sensor device programmed with a computer programme according to claim 26.

32. A sensor device substantially as described with reference to the accompanying examples.

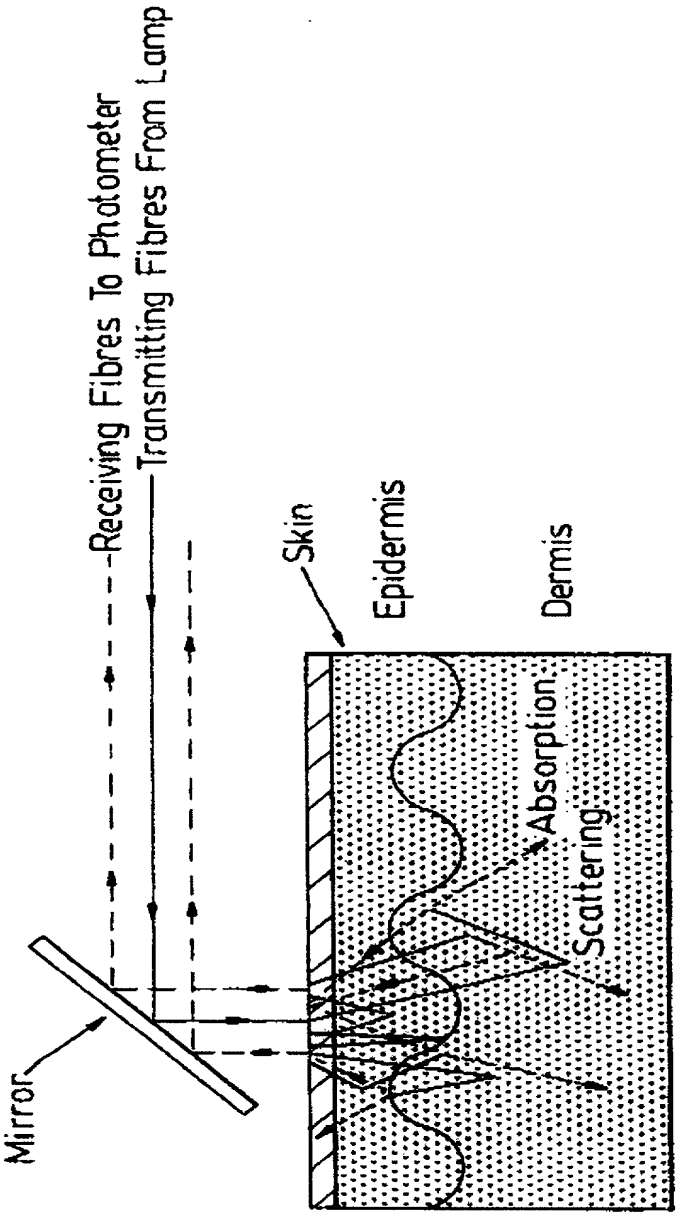
Receiving Fibres To Photometer
Transmitting Fibres From Lamp
Skin
Epidermis
Dermis
Absorption
Scattering
Mirror

Fig. 1

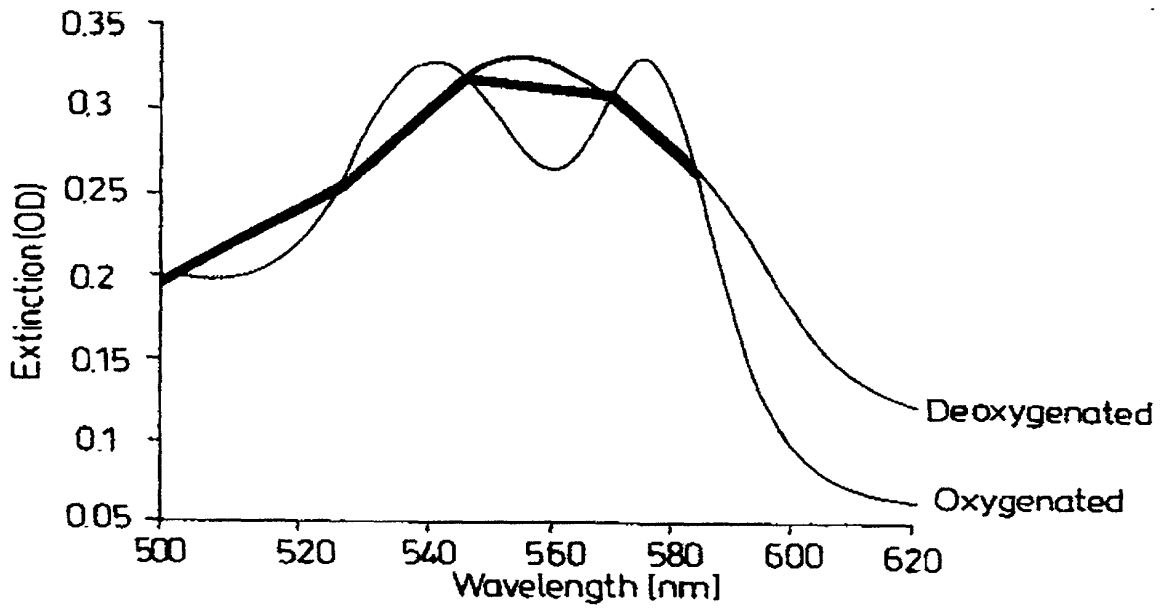
0.35
0.3
0.25
0.2
0.15
0.1
0.05
Extinction (OD)
500
520
540
560
580
600
620
Wavelength [nm]
Deoxygenated
Oxygenated

Fig. 2a

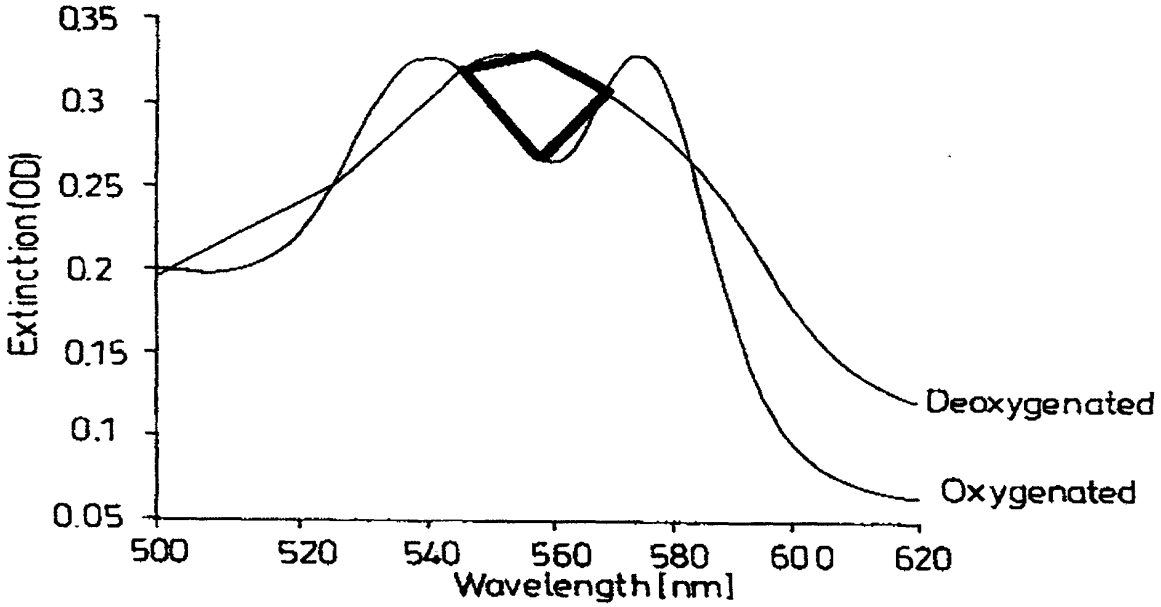
0.35
0.3
0.25
0.2
0.15
0.1
0.05
Extinction (OD)
500
520
540
560
580
600
620
Wavelength [nm]
Deoxygenated
Oxygenated

Fig. 2b

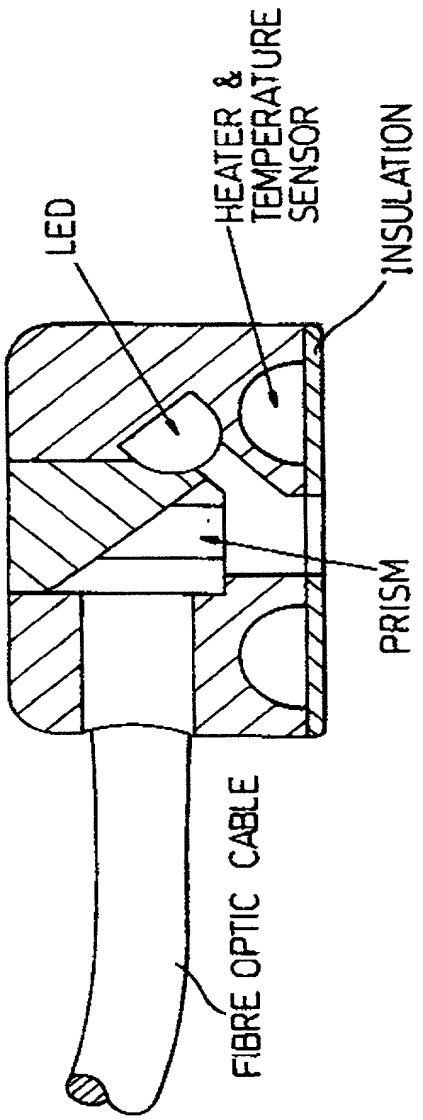
LED
HEATER & TEMPERATURE SENSOR
INSULATION
PRISM
FIBRE OPTIC CABLE

Fig. 3

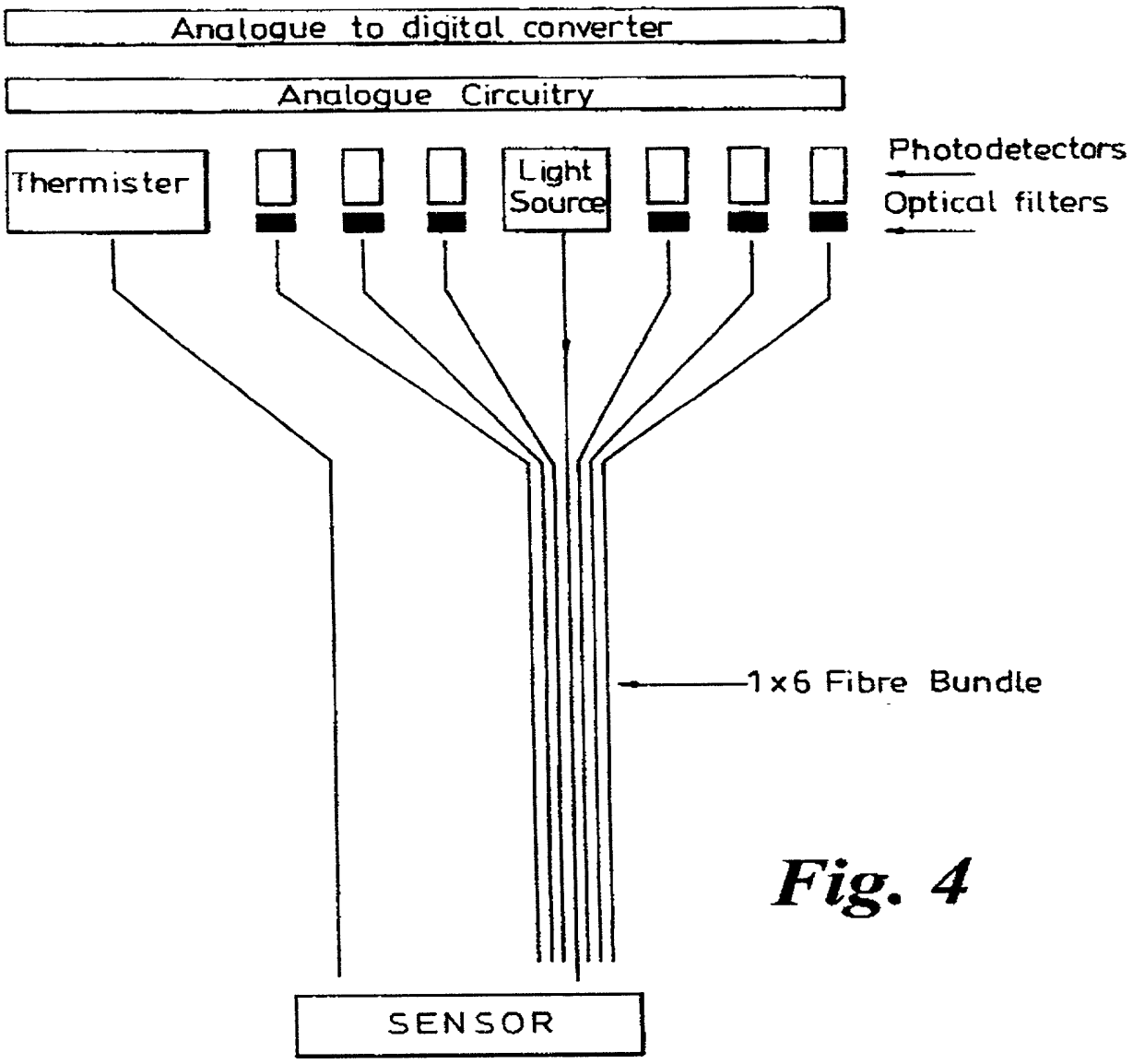
Analogue to digital converter
Analogue Circuitry
Thermister
Light Source
Photodetectors
Optical filters
1x6 Fibre Bundle
SENSOR

Fig. 4

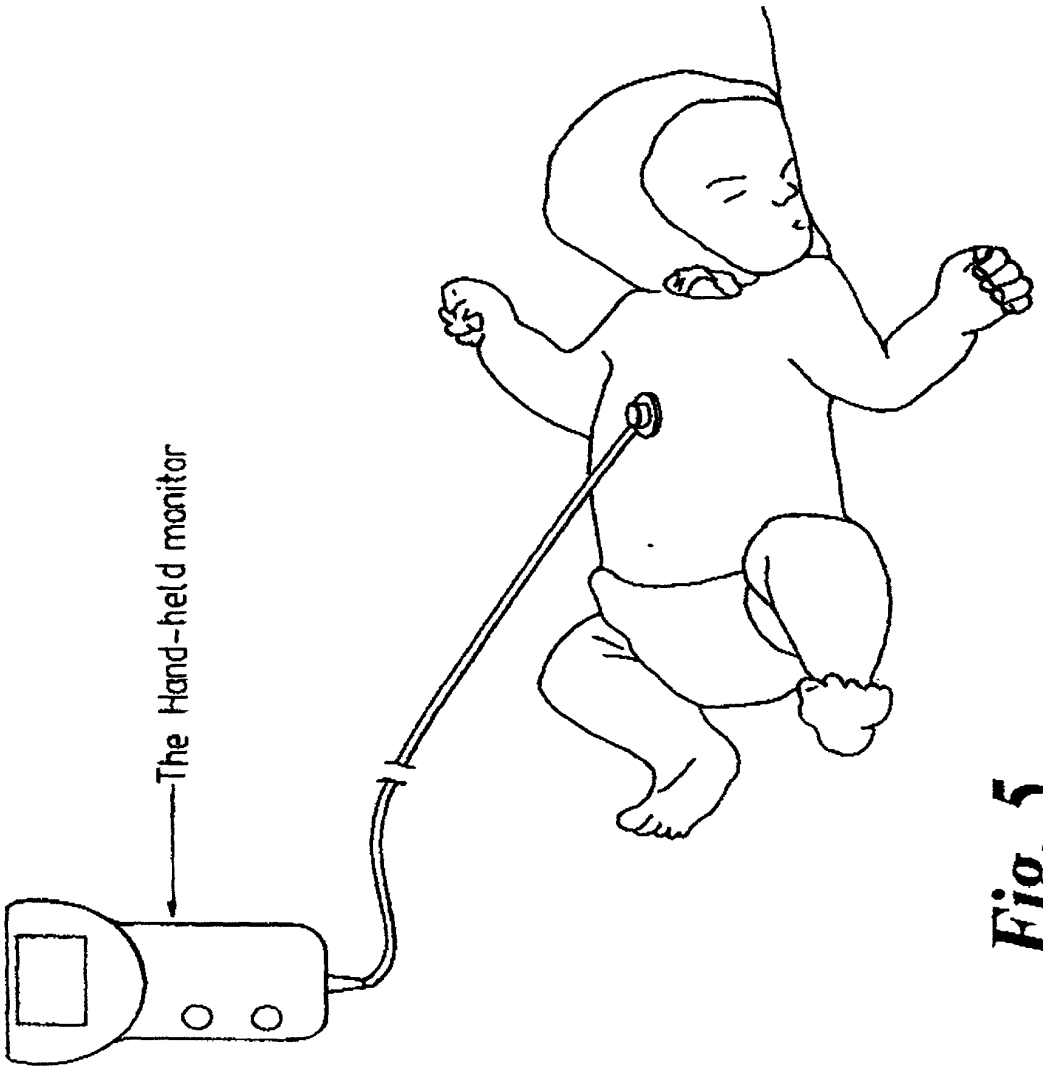

Fig. 5

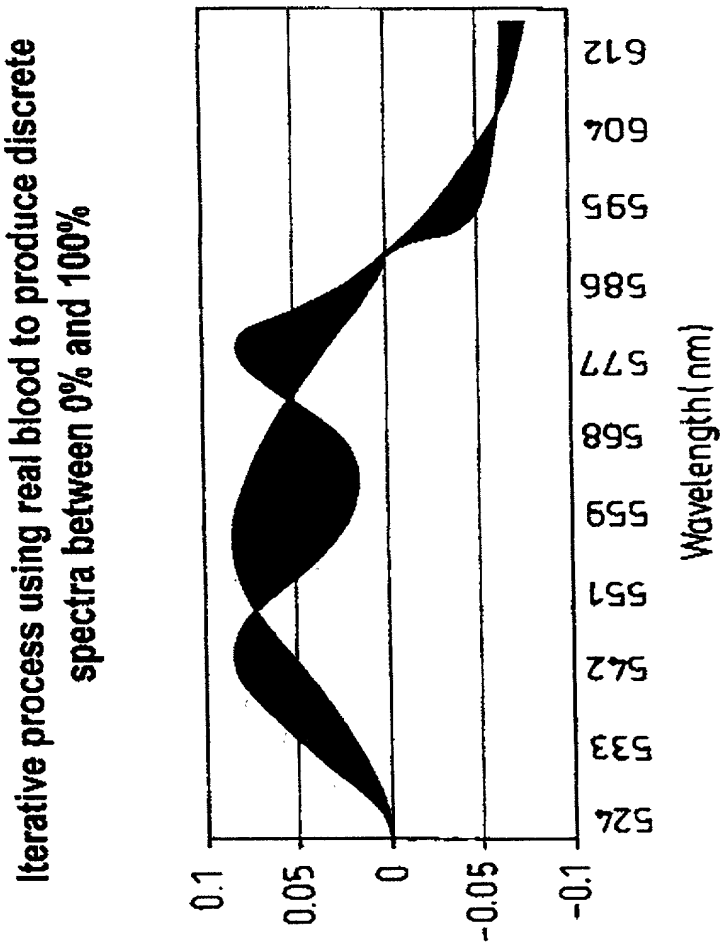
Iterative process using real blood to produce discrete spectra between 0% and 100%
0.1
0.05
0
-0.05
-0.1
524
533
542
551
559
568
577
586
595
604
612
Wavelength(nm)

Fig. 6a

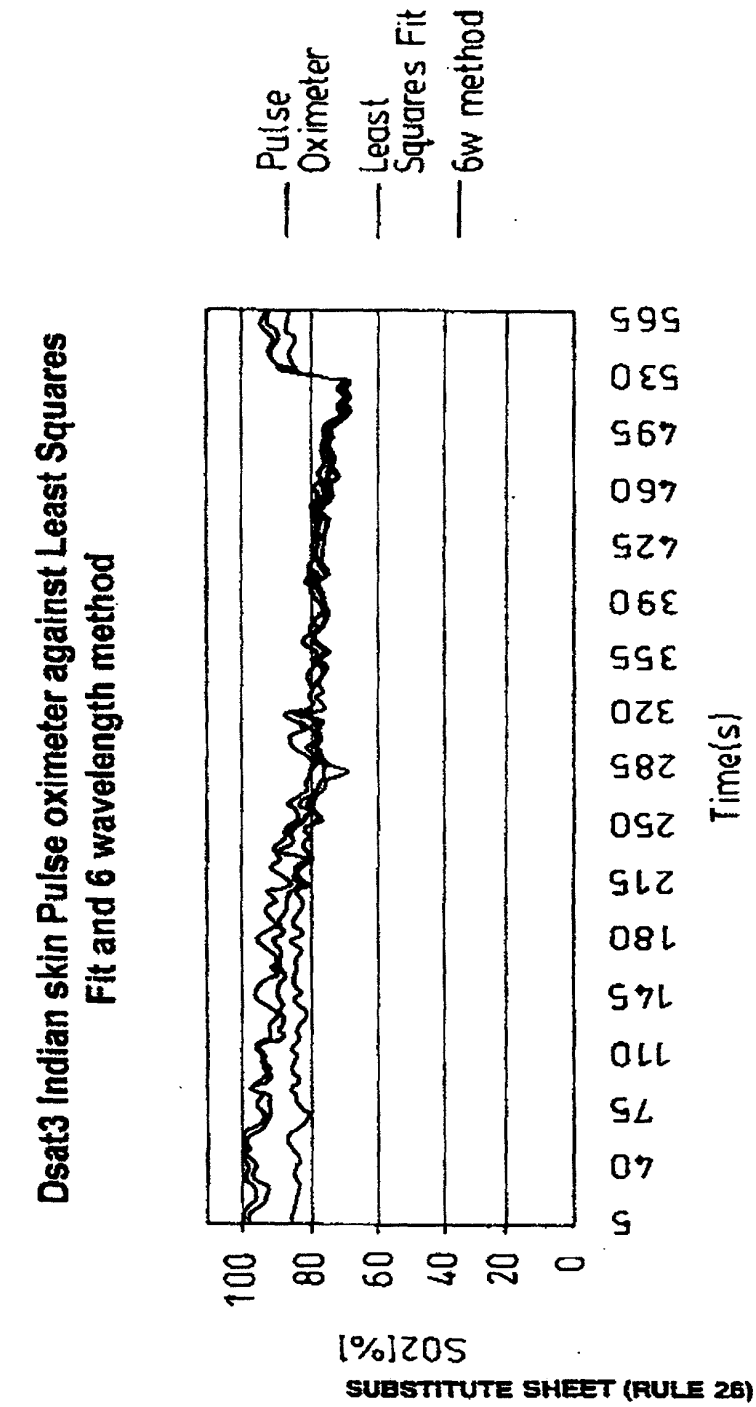
Pulse Oximeter
Least Squares Fit
6w method
Dsat3 Indian skin Pulse oximeter against Least Squares Fit and 6 wavelength method
SO2[%]
100
80
60
40
20
0
Time(s)
5
40
75
110
145
180
215
250
285
320
355
390
425
460
495
530
565

Fig. 6b

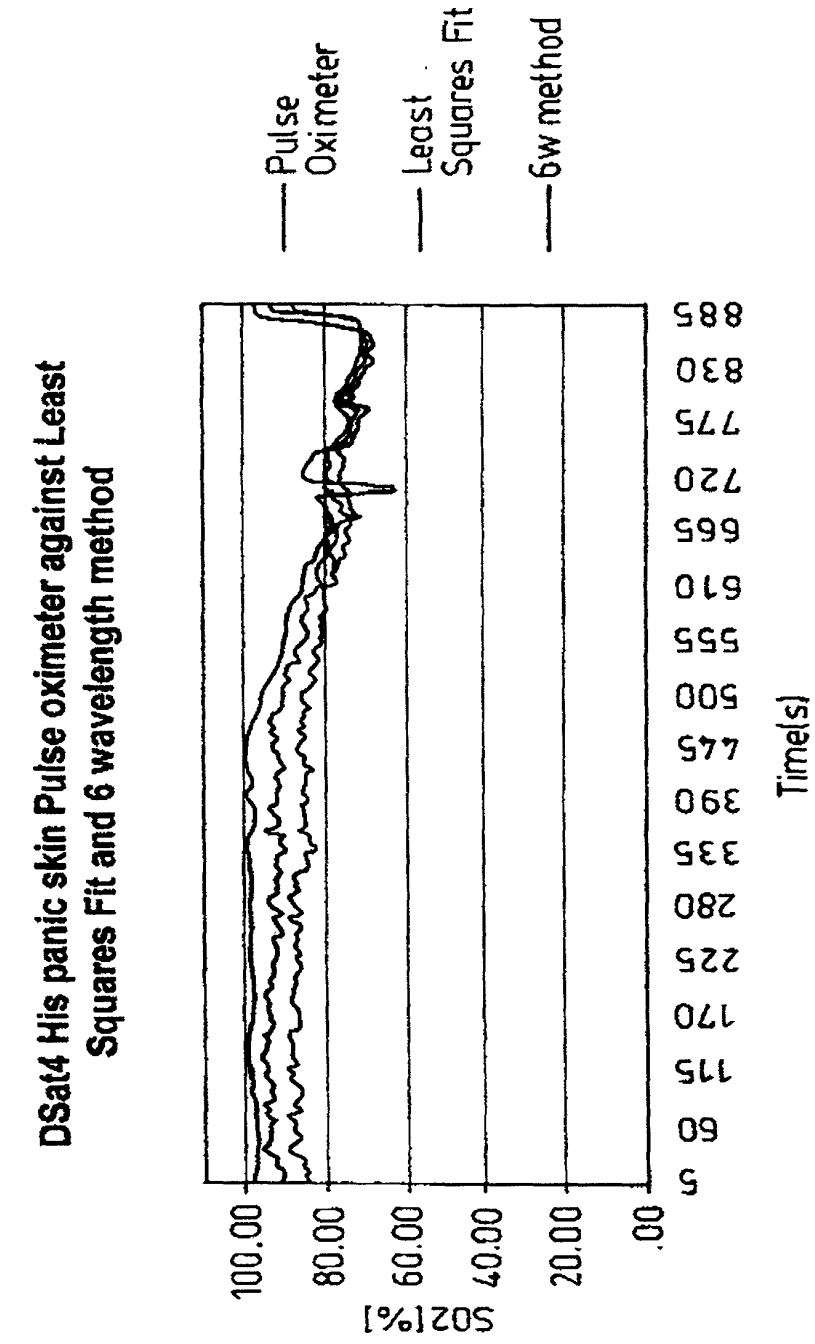
DSat4 His panic skin Pulse oximeter against Least Squares Fit and 6 wavelength method
Pulse Oximeter
Least Squares Fit
6w method
SO2[%]
100.00
80.00
60.00
40.00
20.00
.00
Time(s)
5
60
115
170
225
280
335
390
445
500
555
610
665
720
775
830
885

Fig. 6c

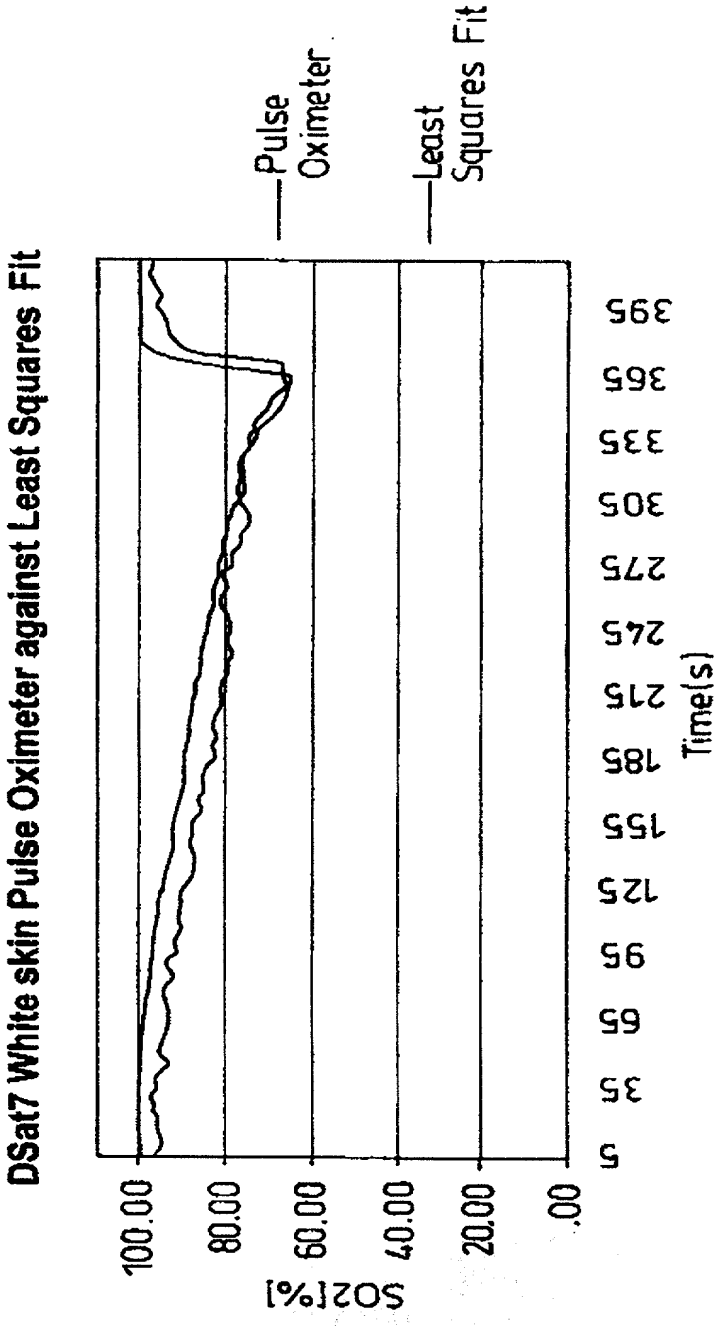
DSat7 White skin Pulse Oximeter against Least Squares Fit
Pulse Oximeter
Least Squares Fit
SO2[%]
100.00
80.00
60.00
40.00
20.00
.00
Time(s)
5
35
65
95
125
155
185
215
245
275
305
335
365
395

Fig. 6d

 #4

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

OPTICAL DEVICE

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on 30 July 1999 as

P.C.T. Application Serial No. PCT/GB99/02510

and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
9817552.4 (Number)	United Kingdom (Country)	13 August 1998 (Day/Month/Year Filed)	☒ Yes	☐ No
9904232.7 (Number)	United Kingdom (Country)	25 February 1999 (Day/Month/Year Filed)	☒ Yes	☐ No
(Number)	(Country)	(Day/Month/Year Filed)	☐ Yes	☐ No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (*list name and registration number*)

1

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Inventor's signature: X	Date: X 4/4/2001
Residence: Dyfed, United Kingdom GBX	
Citizenship: United Kingdom	
Post Office Address: Whitland Abbey	
Whitland, Dyfed SA34 0LG, United Kingdom	
Full name of second joint inventor, if any	
Second inventor's signature	Date
Residence	
Citizenship	
Post Office Address	

(Supply similar information and signature for third and subsequent joint inventors.)